



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																										
Company Name: <input type="text"/> Application: <input type="text"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text"/> Rx Product/Proprietary Name: <input type="text"/> NDC: <input type="text"/> UPC: <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text"/> Active ingredients: <input type="text"/> URL for Additional Product Information: <input type="text"/> Address: <input type="text"/> Address 2: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Zip: <input type="text"/> Key Contact: <input type="text"/> Email: <input type="text"/> Phone Number: <input type="text"/> Fax: <input type="text"/>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/> <input type="checkbox"/> VII. No Requirement																																																										
FOR GENERIC DRUG PRODUCTS		b. Contact for temperature excursion questions:																																																										
I. Orange Book Rating: <input type="text"/> II. Brand Name: <input type="text"/> III. Generic Equivalent for Brand: <input type="text"/>		Name: <input type="text"/> Number: <input type="text"/> Is this product to be shipped to customers on ice? <input type="text"/> Is this product to be shipped to customers on dry ice? <input type="text"/>																																																										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																												
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> DUNS: <input type="text"/> Is product exempt from DSCSA? <input type="text"/> If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text"/> If Yes, was original product purchased direct from mfr? <input type="text"/> Is product sold by manufacturer's exclusive distributor? <input type="text"/> Are any waivers granted for product ID/barcode? <input type="text"/> If yes, attach documentation from FDA		c. Special regulations for product in certain states? Special returns requirements for this product? <input type="text"/> d. Store product (unit of sale) upright? <input type="text"/> Protect product (unit of sale) from light? <input type="text"/> e. Shelf life: <input type="text"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																																										
ADDITIONAL PRODUCT INFORMATION			ITEM AND PACKING INFORMATION																																																									
Is the Product... <input type="text"/> Legend Device? <input type="text"/> State Control? <input type="text"/> ARCOS reportable? <input type="text"/> Co-Licensed? <input type="text"/> Controlled Substance? <input type="text"/> Schedule No.? <input type="text"/> (incl. N for non-narcotic) Controlled Substance Code: <input type="text"/> Hazardous Material/Cytotoxic Agent? <input type="text"/> Is Item... <input type="text"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> Is it reverse numbered? <input type="text"/>			ORDER INFORMATION Unit of Sale <input type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In <input type="text"/> What is the NDC selling unit? <input type="text"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text"/> If Yes, how many of which package type? <input type="text"/> Each <input type="text"/> Inner/Carton/Pack <input type="text"/> Case			<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width: 10%;">Item:</th> <th rowspan="2" style="width: 10%;">Weight Lbs.</th> <th colspan="3" style="width: 40%;">Dimensions (US msmts.)</th> <th rowspan="2" style="width: 10%;">Volume (Cube)</th> <th rowspan="2" style="width: 10%;"># Pieces:</th> </tr> <tr> <th style="width: 10%;">Depth</th> <th style="width: 10%;">Height</th> <th style="width: 10%;">Width:</th> </tr> </thead> <tbody> <tr> <td>Box/ Carton:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Case:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>UPC:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Case:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Carton:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>			Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width:	Box/ Carton:							Case:							Pallet:							UPC:							Case:							Carton:						
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PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION																																																								
Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial)		Size/Strength/Form: <input type="text"/> Product Shape: <input type="text"/> Product Color: <input type="text"/> Product Imprint: <input type="text"/>		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Regular Cost Per Unit of Sale (\$)</th> <th style="width: 33%;">Invoice Cost (WAC) (\$)</th> <th style="width: 33%;">Federal Excise Tax Per Unit of Sale</th> </tr> </thead> <tbody> <tr> <td style="height: 40px;"><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale	<input type="text"/>	<input type="text"/>	<input type="text"/>																																																	
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WHOLESALE USE ONLY:																																																												
Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Finline Code: <input type="text"/>		Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		As of date: <input type="text"/>																																																								

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard?

d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?
RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	RFID	GTIN-14	
<input type="checkbox"/>	<input type="checkbox"/> Item	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/>	<input type="text"/>
If not, when? <input type="text"/>	<input type="checkbox"/> Box/Carton	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/>	<input type="text"/>
Items aggregated to case? <input type="checkbox"/>	<input type="checkbox"/> Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/>	<input type="text"/>
	<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/>	<input type="text"/>

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing	
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>	
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="checkbox"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="checkbox"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>		
<p>REMS or Registry Restrictions</p> <p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> <p>Miscellaneous Notes:</p> <p><input type="text"/></p>	